UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

Plaintiff,

v.

EUROLINE FOODS, LLC,
ROYAL SEAFOOD BAZA, INC.,
EDUARD SHNAYDER,
SYOMA SHNAYDER,
ALBERT NIYAZOV, and
OLEG POLISCHOUK,

Defendants.

Civil Action No.

CV18-2879
COGAN, J.

**COMPLAINT**

Plaintiff, the United States of America, by its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents to this Court as follows:

1. This action is brought by the United States of America under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to enjoin and restrain Euroline Foods, LLC ("Euroline"), a limited liability company; Royal Seafood Baza, Inc. ("Royal Seafood"), a corporation; Eduard Shnayder, Syoma Shnayder, Albert Niyazov, and Oleg Polischouk, individuals (collectively, "Defendants") from violating: (a) 21 U.S.C. § 331(k), by causing food to become adulterated within the meaning of 21 U.S.C. § 342(a)(4) while such food is held for sale after shipment of one or more of its components in interstate commerce; and (b) 21 U.S.C. § 331(a), by causing to be introduced or delivered for introduction into interstate commerce food that is adulterated within the meaning of 21 U.S.C. § 342(a)(4).

## JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and all parties to this action under 21 U.S.C. § 332(a), and 28 U.S.C. §§ 1331, 1337, and 1345.

3. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

## DEFENDANTS

4. Defendant Euroline is a Delaware limited liability company operating a seafood processing facility at 175 Lake Avenue, Staten Island, New York, 10303-2727 ("Euroline/Royal Seafood Facility") within the jurisdiction of this Court. Defendant Euroline's business offices are located at 1601 Gravesend Neck Road, Brooklyn, New York, 11229, within the jurisdiction of this Court. Defendant Euroline came into existence on or about May 24, 2016, and is the functional successor to most of Royal Seafood's food processing operations. A majority of defendant Euroline is owned by GMI Holding, LLC. Individual defendants Eduard Shnayder, Syoma Shnayder, and Albert Niyazov collectively own a majority interest in GMI Holding, LLC.

5. Defendant Royal Seafood is a New York corporation operating a seafood processing facility at 175 Lake Avenue, Staten Island, New York, 10303-2727 ("Euroline/Royal Seafood Facility") within the jurisdiction of this Court. Defendant Royal Seafood's business offices are located at 1601 Gravesend Neck Road, Suite 15, Brooklyn, New York, 11229, within the jurisdiction of this Court. Defendant Royal Seafood is wholly owned by GMI Holding, LLC.

6. Defendant Eduard Shnayder is Royal Seafood's Chief Executive Officer, a majority co-owner of Royal Seafood, and a co-owner of Euroline. He shares responsibilities for Euroline's and Royal Seafood's business operations and oversees all aspects of the companies along with Euroline's and Royal Seafood's other owners. He performs his duties at 1601

Gravesend Neck Road, Suite 15, Brooklyn, New York, 11229, within the jurisdiction of this Court.

7. Defendant Syoma Shnayder is a majority co-owner of Royal Seafood and a co-owner of Euroline. She shares responsibilities for the business operations of Euroline and Royal Seafood, and she oversees all aspects of the companies along with Euroline's and Royal Seafood's other owners. She performs her duties at 1601 Gravesend Neck Road, Suite 15, Brooklyn, New York, 11229, within the jurisdiction of this Court.

8. Defendant Albert Niyazov is the General Manager and a co-owner of both Euroline and Royal Seafood. He oversees the day-to-day operations of both companies, and he also is responsible for preventing, detecting, and correcting objectionable practices and conditions. He shares responsibilities for the business operations of Euroline and Royal Seafood, and he oversees all aspects of the companies with Euroline's and Royal Seafood's other owners. He performs his duties at the Euroline/Royal Seafood Facility, within the jurisdiction of this Court.

9. Defendant Oleg Polischouk is the Manager of Euroline and Royal Seafood. He oversees the day-to-day operations of Euroline and Royal Seafood, including seafood Hazard Analysis and Critical Control Point ("HACCP") compliance, employees, production, sanitation, and purchases. He performs his duties at the Euroline/Royal Seafood Facility, within the jurisdiction of this Court.

10. Defendants prepare, process, pack, hold, and distribute more than 8,000 products, including ready-to-eat fish and fishery products (pickled herring and caviar), ready-to-eat vegetable salads, and cheese products.

11. Defendants receive fish for their ready-to-eat fish and fishery products from outside New York, including, but not limited to, salmon from Washington and Chinese flounder shipped from a Pennsylvania importer. Defendants also cause their fish and fishery products to be introduced into interstate commerce, including to New Jersey, Pennsylvania, Ohio, Oregon, Texas, and North Carolina.

## FOOD SAFETY

12. *Listeria monocytogenes* ("*L. mono*") is the bacterium that causes listeriosis, a disease commonly contracted by eating food contaminated with *L. mono*. Listeriosis can be serious, even fatal, for vulnerable groups such as newborns and those with impaired immune systems. The most serious forms of listeriosis can result in meningitis and septicemia. Pregnant women may contract flu-like symptoms from listeriosis, and complications from the disease can result in miscarriage or septicemia, i.e., blood poisoning, in the newborn.

13. Unlike many other foodborne microbes, *L. mono* can adapt and grow at refrigeration temperatures or under other adverse conditions, such as high-salt or high-acid (low pH) conditions. The presence of *L. mono* in a facility processing ready-to-eat foods presents a particularly significant public health risk.

14. To minimize the potential for *L. mono* contamination, it is necessary to have sanitation procedures that prevent contamination of food contact surfaces and to eliminate niches where *L. mono* can become established, grow, and persist. Strict in-plant sanitation measures must be taken to eliminate *L. mono* and prevent its proliferation. *L. mono* can persist for years in processing environments that have suspended operations if not properly eliminated through strict sanitation measures.

15. *Clostridium botulinum* ("*C. bot.*") is an anaerobic bacterium, meaning that it thrives in oxygen-free environments. All people are susceptible to the neurotoxin that *C. bot.* spores can produce in food. Ingesting even a small amount of this neurotoxin can cause botulism poisoning. Although the incidence of botulism is rare, the disease can cause paralysis and has a high mortality rate if not treated promptly.

16. *C. bot.* is a pathogen that is widely distributed in nature and may be found in any raw fish or fishery product. Because its spores are heat-resistant, *C. bot.* can survive cooking. *C. bot.* can also survive in food that has been incorrectly or minimally processed. Certain strains of *C. bot.*, called proteolytic strains, produce offensive odors and tastes in food products and can grow at temperatures as low as 50°F. In contrast, non-proteolytic strains of *C. bot.* do not produce the same sensory signals. These non-proteolytic strains are particularly dangerous because they can grow and produce toxin at refrigeration temperatures as low as 38°F, rendering a food toxic without any signs of spoilage. Toxin formation by non-proteolytic *C. bot.* can occur at temperatures above 38°F. To inhibit the growth of non-proteolytic *C. bot.*, processors must employ adequate levels of salt or salt-nitrite combinations in brining solutions in conjunction with proper smoking and drying, in addition to adequate refrigeration temperatures.

17. The Act and its implementing regulations require a seafood processor to control the risk of *C. bot.* and *L. mono* formation if the bacteria are reasonably likely to grow in the processor's seafood products. *See* 21 U.S.C. § 342(a)(4); 21 C.F.R. §§ 123.6(a)-(c).

18. The hazard of scombrotoxin (histamine) formation is reasonably likely to occur post-mortem in certain types of fish, including herring, that are not chilled rapidly or stored at sufficiently low temperatures. Although the toxin can be adequately controlled when fish are promptly chilled after death and maintained at a cold temperature through storage and

distribution, in the event of moderate to severe temperature abuse, scombrotoxin forms readily and cannot be removed or destroyed by washing, freezing, or cooking the fish.

19. Consuming fish containing high levels of scombrotoxin may cause scombrotoxin poisoning, the symptoms of which may include burning in or around the mouth or throat, dizziness, nausea, vomiting, headaches, diarrhea, rashes, hives, a drop in blood pressure, and, in severe cases, asthmatic-like constriction of the air passage, heart palpitations, and respiratory distress.

20. The Act and its implementing regulations require a seafood processor to control the risk of scombrotoxin formation if it is reasonably likely to form in the processor's seafood products. 21 C.F.R. § 123.6(a)-(c).

## REGULATORY FRAMEWORK

21. Defendants' ready-to-eat fish and fishery products, ready-to-eat vegetable salads, and cheese products are "food" within the meaning of the Act. *See* 21 U.S.C. § 321(f).

22. Food is adulterated within the meaning of 21 U.S.C. § 342(a)(4) "if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health."

23. A seafood processor's failure to comply with the requirements of the seafood Hazard Analysis and Critical Control Point ("HACCP") regulations, 21 C.F.R. Part 123, renders its fish or fishery products adulterated under the Act. *See* 21 U.S.C. § 342(a)(4); 21 C.F.R. §§ 123.6(g), 123.12(d).

24. The seafood HACCP regulations require every fish and fishery product processor to "conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur" during the processing of each kind of fish or

fishery product that it processes. 21 C.F.R. § 123.6(a). A food safety hazard is "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." 21 C.F.R. § 123.3(f).

25. Whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur during processing, the processor must develop and implement an adequate HACCP plan to control the identified food safety hazards. 21 C.F.R. § 123.6(b). Among other things, a HACCP plan must:

A. Identify critical control points ("CCPs"), which are points, steps, or procedures in a food manufacturing process at which controls can be applied to prevent, eliminate, or reduce a food safety hazard to an acceptable level. *See* 21 C.F.R. §§ 123.3(b) and 123.6(c)(2); and

B. Identify critical limits at each CCP, which are the maximum or minimum values within which a physical, biological or chemical parameter must be maintained to prevent, eliminate, or reduce to an acceptable level, the occurrence of the identified food safety hazard(s). *See* 21 C.F.R. §§ 123.3(c) and 123.6(c)(3).

26. A seafood processor must also:

A. Take corrective action whenever a deviation from a critical limit occurs, 21 C.F.R. § 123.7;

B. Verify that its HACCP plan is adequate to control food safety hazards reasonably likely to occur and that the plan is being effectively implemented, 21 C.F.R. § 123.8(a);

C. Record its sanitation activities, 21 C.F.R. § 123.11(c), and maintain additional appropriate records, such as documentation of CCPs, corrective actions taken, and HACCP plan verification activities, 21 C.F.R. §§ 123.6-123.9; and

D. Monitor, with sufficient frequency, sanitation controls and practices used during processing to ensure that they conform with the food cGMP requirements, including prevention of cross-contamination from insanitary objects and exclusion of pests. 21 C.F.R. § 123.11(b) and 21 C.F.R. Part 110.

27. Defendants are subject to the seafood HACCP regulations because they engage in the "processing," as defined at 21 C.F.R. § 123.3(k)(1), of "fish" or "fishery product," as defined at 21 C.F.R. §§ 123.3(d) and (e).

28. Food is adulterated under 21 U.S.C. § 342(a)(4) if it is prepared, packed, or held in a facility that does not comply with Current Good Manufacturing Practice ("cGMP") regulations for food, 21 C.F.R. Part 110. *See* 21 C.F.R. § 110.5(a).

29. It is a violation of the Act, 21 U.S.C. § 331(k), to cause articles of food that are held for sale after shipment of one or more components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4).

## DEFENDANTS' VIOLATIONS

30. Defendants violate 21 U.S.C. § 331(k) by causing articles of food to become adulterated within the meaning of 21 U.S.C. § 342(a)(4) while such articles are held for sale after shipment of one or more components in interstate commerce.

31. Defendants violate 21 U.S.C. § 331(a) by causing the introduction or delivery for introduction into interstate commerce of articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4).

32. Defendants' food is adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that it has been prepared, packed or held under insanitary conditions whereby it may have

become contaminated with filth or may have been rendered injurious to health. Such insanitary conditions include:

A. Defendants' failure to comply with the seafood HACCP regulations, 21 C.F.R. Part 123, by, among other deficiencies, failing to adequately control the risk of *C. bot.* and scombrotoxin (histamine) formation in susceptible fish and fishery products and failing to monitor sanitation conditions and practices during processing with sufficient frequency;

B. Defendant's failure to implement effective sanitation controls in accordance with food cGMP requirements, 21 C.F.R. Part 110; and

C. Persistent presence of *L. mono* in the Euroline/Royal Seafood Facility, including near food-contact surfaces.

## HISTORY OF VIOLATIONS

33. FDA inspected the Euroline/Royal Seafood Facility three times: March 2015, February-March 2016, and November-December 2016. During each of the three inspections, the FDA investigator found the same or similar types of insanitary conditions, as well as repeated violations of the Act and seafood HACCP and cGMP regulations. In November 2017, FDA conducted a follow-up investigation of the Euroline/Royal Seafood Facility, and found continuing violations of the Act and seafood HACCP and cGMP regulations.

### March 2015 and February-March 2016 Inspections

34. FDA inspected the Euroline/Royal Seafood Facility in March 2015 and again in February-March 2016. During both inspections, FDA observed and documented significant HACCP and cGMP deficiencies.

35. At the close of the March 2015 inspection, FDA investigators issued to defendant Niyazov a written List of Inspectional Observations ("Form FDA 483"), which included but was not limited to the following observations:

A. Failure to have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur, in violation of 21 C.F.R. § 123.6(c)(1);

B. Failure to have a HACCP plan that lists the critical limits that must be met at each control point, in violation of 21 C.F.R. § 123.6(c)(2); and

C. Failure to implement the monitoring and recordkeeping procedures in the written HACCP plans to control food safety hazards, in violation of 21 CFR § 123.6(b). Among other details, the March 19, 2015 Form FDA 483 explained that the facility was "not monitoring, documenting or reviewing temperature values for seafood products stored under refrigeration with sufficient frequency to assure control of the identified food safety hazards of Bacterial Pathogen growth, Clostridium botulinum growth, and Scombrotoxin formation identified in your written HACCP plans."

D. Failure to take corrective action, by following the procedures in 21 CFR § 123.7, to ensure affected product was not entered into commerce in response to private laboratory findings indicating that water-phase salt content of various fish samples deviated from requirements in the facility's HACCP plan, as required by 21 CFR § 123.8(b); and

E. Failure to monitor sanitation conditions and practices during processing with sufficient frequency to ensure conformance with cGMP, including prevention of cross-contamination from insanitary objects, and protection of food, food packaging material, and food contact surfaces from adulteration in violation of 21 C.F.R. § 123.11(b).

36. On April 30, 2015, the FDA received Defendants' response to the Form FDA 483 issued by the FDA investigator on March 19, 2015. On or about October 20, 2015, FDA issued a Warning Letter, which notified Defendants that they were in violation of seafood HACCP regulations, causing their products to be adulterated under the Act. The Warning Letter also noted the deficiencies in Defendants' proposed corrective actions, which had been outlined in their response to the March 19, 2015 Form FDA 483. The Warning Letter cautioned Defendants that, if they failed to promptly correct their violations, FDA may pursue further regulatory action, including seeking an injunction.

37. During the February-March 2016 inspection, FDA noted that *L. mono* was detected in several areas of the herring processing rooms and in the vegetable/pickled processing room. At the close of the February-March 2016 inspection, FDA investigators issued to defendant Niyazov a twelve-item Form FDA 483, including but not limited to the following observations:

A. Failure to have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur, in violation of 21 C.F.R. § 123.6(c)(1). As noted above, this observation had been documented during FDA's March 2015 inspection, and in FDA's October 20, 2015 Warning Letter;

B. Failure to have a HACCP plan that lists the critical limits that must be met at each control point, in violation of 21 C.F.R. § 123.6(c)(2). As noted above, this observation also was documented during the March 2015 Inspection;

C. Failure to implement the monitoring and recordkeeping procedures in the written HACCP plans to control food safety hazards, in violation of 21 CFR § 123.6(b). As noted above, this observation was also documented during the March 2015 Inspection; and

D. Failure to monitor sanitation conditions and practices during processing with sufficient frequency to ensure conformance with cGMP, including prevention of cross-contamination from insanitary objects, and protection of food, food packaging material, and food contact surfaces from adulteration in violation of 21 C.F.R. § 123.11(b), as evidenced by Defendants' failure to comply with the following cGMP requirements:

i. Failure to construct the Euroline/Royal Seafood Facility in such a manner that floors may be adequately cleaned and kept clean and in good repair and sufficient to prevent food from becoming adulterated. 21 C.F.R. §§ 110.20(b)(4) and 110.35(a);

ii. Failure to protect work in-process from contamination and failing to prevent cross-contamination from insanitary objects. 21 C.F.R. § 110.80(b)(5);

iii. Failure to provide and adequately monitor sanitary facilities, including hand-washing, toilet, and hand-sanitizing facilities. 21 C.F.R. § 110.37;

iv. Failure to clean food-contact surfaces as frequently as necessary to prevent against contamination of food. 21 C.F.R. § 110.35(d) and 110.80(b); and

v. Failure to monitor protection of food, food packaging material, and food contact surfaces from adulteration. 21 C.F.R. § 110.80(b).

38. At the close of both the March 2015 and the February-March 2016 inspections, FDA investigators discussed their observations of objectionable conditions and practices at the Euroline/Royal Seafood Facility with defendant Niyazov, and on each occasion presented a Form FDA 483 to him.

39. Defendant Niyazov responded to the Form FDA 483 and Warning Letter acknowledging the violations and promising to take corrective action.

November-December 2016 Inspection

40. During FDA's inspection of Defendants' Euroline/Royal Seafood Facility between November 9 and December 6, 2016, an FDA investigator documented significant HACCP and cGMP deficiencies. When the inspection ended, FDA investigators issued to defendant Niyazov a Form FDA 483 that included the following observations:

A. Failure to implement the monitoring, recordkeeping, and verification procedures listed in Defendants' HACCP plans to control food safety hazards, in violation of 21 CFR §§ 123.6(b), (c)(4), (c)(7) and 21 C.F.R. § 123.8(a); and

B. Failure to monitor sanitation conditions and practices during processing with sufficient frequency to ensure conformance with cGMP, including prevention of cross-contamination from insanitary objects and prevention of pests in violation of 21 C.F.R. § 123.11(b), as evidenced by Defendants' failure to comply with the following cGMP requirements:

i. Failure to provide adequate cleaning to protect against introduction of microorganisms into food. 21 C.F.R. § 110.35(d);

ii. Failure to provide adequate protection against pests. 21 C.F.R. § 110.35(c); and

iii. Failure to protect work-in-process from contamination and failure to prevent cross-contamination from insanitary objects. 21 C.F.R. § 110.80(b)(5).

41. Defendants' deficient cleaning and sanitation practices had led to the contamination of surfaces near food preparation areas with pathogenic bacteria. FDA's analysis of environmental samples collected during the November-December 2016 inspection revealed the presence of *L. mono* contamination in multiple locations throughout the Euroline/Royal

Seafood Facility. Strict in-plant measures are necessary to control *L. mono*'s proliferation in the Euroline/Royal Seafood Facility and to protect the public health.

2017 Follow-Up Investigation

42. FDA conducted an investigation between November 1 and 6, 2017, to verify the scope of Euroline and Royal Seafood's current operations.

43. At the time of the 2017 follow-up investigation, FDA confirmed that Defendants were not using the processing area and equipment in the Euroline/Royal Seafood Facility. However, the equipment was fully functional, and the processing area appeared to be ready to use at any time.

44. The FDA investigator noted continuing HACCP and cGMP deficiencies, despite Defendants' apparent decision to shut down its processing area and discontinue use of its processing equipment. These deficiencies included:

A. Failure to implement the monitoring, recordkeeping, and verification procedures listed in Royal Seafood's HACCP plans to control food safety hazards, in violation of 21 C.F.R. § 123.6(b), c(7); and

B. Failure to monitor sanitation conditions and practices during receipt and storage of seafood products with sufficient frequency to ensure conformance with cGMP, including prevention of cross-contamination from insanitary objects and protection of food from adulteration in violation of 21 C.F.R. § 123.11(b).

45. During the investigation, defendant Niyazov acknowledged the violations and promised to take corrective action. As evidenced by Defendants' repeated violations observed during this 2017 investigation, including the failure to monitor and record sanitation conditions,

Defendants failed to take effective measures to bring their food operations into compliance with the law.

46. As evidenced by the prior findings of *L. mono* in the food processing area and the repetitive violations observed during FDA's 2016 and 2017 inspections, Defendants have failed to take effective measures to bring their food processing operations into compliance with the law.

47. The United States believes that, unless restrained by order of this Court, Defendants will continue to violate 21 U.S.C. § 331(k) and (a).

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships), cease receiving, preparing, processing, packing, holding, or distributing articles of food unless and until Defendants bring their receiving, preparing, processing, packing, holding, and distributing food at or from the Euroline/Royal Seafood Facility or at any other location(s) at or from which Defendants, now or in the future, receive, prepare, process, pack, hold, and/or distribute food, into compliance with the Act and applicable regulations, to FDA's satisfaction;

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships), from

directly or indirectly violating 21 U.S.C. §§ 331(a) or (k), by causing articles of food that are held for sale after shipment of one or more components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4), or by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, adulterated articles of food into interstate commerce, within the meaning of 21 U.S.C. § 342(a)(4);

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' place(s) of business and all records relating to the importing, receiving, preparing, processing, packing, holding, and distribution of food, to ensure continuing compliance with the terms of the injunction, the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Order that Plaintiff be awarded costs incurred in pursuing this action, including the costs of investigation to date, and such other equitable relief as the Court deems just and proper.

DATED this 21st day of May, 2018.

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